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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,924	11/16/2001	Gregory H. Altman	19471-502 (TRI-2)	4778

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NAFF, DAVID M

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/008,924	Applicant(s) Altman et al
	Examiner Nafft	Group Art Unit 1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 1/23/03.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-174 is/are pending in the application.

Of the above claim(s) 81-127 + 138-173 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-80, 128-137 + 174 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Notice of Reference(s) Cited, PTO-892

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

In a response of 1/23/03, applicants elected Group I claims 1-80, 128-137 and 174 without traverse.

Claims 81-127 and 138-173 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7 of 1/23/03.

Claims examined on the merits are 1-80, 128-137 and 174.

Applicant is advised that should claims 1-16 be found allowable, claims 33, 49 and 69, and claims dependent on claims 33, 49 and 69 that correspond to claims dependent on claim 1 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The silk-fiber-based matrix of claims 33, 49 and 69 is the same as required by claim 1. Setting forth a different intended use in claims 33, 49 and 69 does not make the matrix different. To be different, the matrix, per se, must be required to have different physical and/or chemical characteristics.

Applicant is advised that should claim 8 be found allowable, claim 17 and any claims dependent on claim 17 corresponding to any claims dependent on claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same

thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 8 requires the matrix to be seeded with pluripotent or fibroblast cells, and this is required in claim 17.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-80, 128-137 and 174 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by reciting "wire-rope geometry" which is uncertain as to meaning and scope, and is unclear as to structure required. Such language does not appear to be art recognized for defining a particular structure.

Claims 1-16 are confusing and unclear by "predetermined type" in claim 1 being uncertain as to meaning and scope. Being "predetermined" and a "type" is relative and subjective and does not define the ligament or tendon produced. It is suggested that "predetermined" and "type" be deleted in claim 1 and where occurring in other claims.

Claim 1 is further unclear how the intended use of producing a predetermined ligament or tendon *ex vivo* defines the silk-fiber-based

matrix since how the ligament or tendon is produced is not set forth. Additionally, requiring producing ligament or tendon is confusing since the specification describes producing ligament or tendon tissue. In line 2 of claim 1, -- tissue -- should be inserted after "tendon". This change should also be made to claims 33, 49, 69 and 128, and to any other claims where ligament or tendon is recited. Claim 1 should additionally require producing the ligament or tendon tissue by seeding the matrix with pluripotent or fibroblast cells and culturing the cells *in vitro* to produce the ligament or tendon tissue.

Claim 9 is confusing by depending on claim 9.

Claims 33 and 49 are unclear how the matrix being seeded with cells and the cells cultured define the matrix. It is unclear as to whether being seeded and cultured is to be part of the intended use or to require cultured cells in combination with the matrix. If intended to be part of the intended use, the use should require seeding with the cells and culturing the cells as claimed. If cultured cells are to be part of the matrix, this should be made clear.

Claims 49 and 69 are unclear by reciting "ligament or tissue" since ligament is tissue. If any tissue can be produced, the claims should require producing tissue, and in a dependent claim require the tissue to be ligament tissue. In line 3 of claim 69, "ligament or tendon" is recited, whereas, "ligament or tissue" is recited in line 2. This is confusing.

Claim 69 is unclear by requiring exposing seeded cells to dynamic mechanical signals from a subject since it is unclear how this is accomplished.

Claims 128-137 are unclear by claim 128 requiring bioengineered tissue and requiring cells to be seeded on the matrix without producing the tissue. The claim should require the tissue to be formed by seeding the matrix with the cells and culturing the cells *in vitro* on the matrix to form ligament or tendon tissue. In line 1 of claim 128, -- ligament or tendon -- should be inserted before "tissue" since the last line requires ligament or tendon to be formed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 8-19, 21, 24-36, 38, 41-56, 58, 61-71, 73, 76-80, 128, 129, 133-137 and 174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (6,303,136 B1) in view of Lewis et al (5,994,099) and Takezawa et al (5,736,399).

The claims are drawn to a silk-fiber-based matrix having a wire-rope geometry for use in producing ligament or tendon tissue.

Li et al disclose attaching cells to a filamentous matrix that can be made from various materials including silk (col 2, line 49 and col 4, line 18).

Lewis et al disclose preparing a matrix from silk for use in reconstruction of bone and connective tissue (col 21, lines 1-5).

Takezawa et al disclose using a silk mesh as a culture carrier (col 5, lines 56-60).

It would have been obvious to prepare the filamentous matrix of Li et al from silk in view of Lewis et al suggesting preparing a matrix for tissue reconstruction from silk and Takezawa et al using a silk mesh as a culture carrier. The filamentous matrix of Li et al would inherently have a wire-rope geometry and be capable of use to produce ligament or tendon tissue *in vitro*. Seeding the matrix with specific cells would have been a matter of obvious choice depending on the type of tissue being produced. Forming bioengineered tissue using the matrix would have been obvious since this is a well known use of such a matrix.

Claim Rejections - 35 USC § 103

Claims 4, 6, 20, 22, 37, 39, 57, 59, 72, 74, 130 and 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references

as applied to claims 1-3, 5, 8-19, 21, 24-36, 38, 41-56, 58, 61-71, 73, 76-80, 128, 129, 133-137 and 174 above, and further in view of Mansmann (6,530,956 B1).

The claims require the matrix to contain collagen fibers or be a composite of silk and a degradable polymer such as collagen.

Mansmann discloses a matrix prepared from collagen fibers (col 8, lines 35-40).

It would have been obvious to use collagen fibers in combination with the filamentous silk matrix of Li et al or use collagen to form a composite with the silk of Li et al in view of Mansmann disclosing preparing a matrix from collagen fibers and Li et al suggesting coating the silk matrix with collagen (col 2, lines 59).

Claim Rejections - 35 USC § 103

Claims 7, 23, 40, 60, 75 and 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-3, 5, 8-19, 21, 24-36, 38, 41-56, 58, 61-71, 73, 76-80, 128, 129, 133-137 and 174 above, and further in view of Shalaby et al (4,461,298).

The claims require the matrix to contain a composite of silk and a nondegradable polymer.

Shalaby et al disclose forming a composite of silk and another polymer to form a composite suture.

It would have been obvious to use a nondegradable polymer in combination with silk in the matrix of Li et al as suggested by Shalaby et al forming a composite suture from silk and another polymer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1281

DMN
4/18/03